



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

inder the Paperwood Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB co

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 1 of 2

| a collection of information unless it displays | a valid OMB control number. |
|--|-----------------------------|
| Application Number | 09/709,069 |
| Filing Date | 9 November 2000 |
| First Named Inventor | Joseph R. Codispoti |
| Group Art Unit | 1614 |
| Examiner Name | D. Jagoe |
| Attorney Docket Number | MCP-264 |

| | | r- | | U.S. PATENT DOCUMENTS | | |
|---------------|------|-----------------|------------------------|-------------------------------|---------------------------------------|--|
| Examiner Cite | | U.S. Patent Doo | Kind Code ² | Name of Patentee or Applicant | Date of Publication of Cited Document | Pages, Columns, Lines, where relevant passages |
| Initials | No.1 | Number | (if known) | of Cited Document | mm-dd-yyyy | where relevant passages or relevant inures enpear |
| W | | 3,987,170 | | Rohrbach et al. | 10-19-1976 | -00 |
| | | 5,914,129 | | Mauskop | 6-22-1999 | DEC 0 4 |
| | | 5,538,959 | | Mauskop | 7-23-1996 | TECH CENTER 16 |
| | | 5,773,031 | | Shah et al. | 6-30-1998 | 32141LN 16 |
| | | 5,965,166 | | Hunter et al. | 10-12-1999 | |
| | | 5,837,729 | | Bourinbaiar | 11-17-1998 | |
| <u> </u> | | 6,060,499 | | Plachetka | 5-09-2000 | |
| 120 | | 5,872,145 | | Plachetka | 2-16-1999 | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

FOREIGN PATENT DOCUMENTS Pages, Columns, Lines, Foreign Patent Document Date of Publication of Cited Document where relevant Name of Patentee or Examiner Cite passages or relevant mm-dd-yyyy Applicant of Cited Document Initials figures appear No.1 Office³ Number⁴ KindCode⁵ GB 1514225 Bottu 6-14-1978 wo 98/38983 A2 Smithkline Beecham PLC 9-11-1998 EP 0753296 A2 American Home Products 1-15-1997 Corporation

| | A | | <i></i> |
|--------------------|-------|-----------------------|---------|
| Examiner Signature | Um Ja | Date Considered // | 10/03 |
| | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.





PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE to a collection of information unless it displays a valid OMR control or unless.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 2

| a collection of information unless it displays a | Valid OMB contion number. |
|--|---------------------------|
| Application Number | 09/709,069 |
| Filing Date | 9 November 2000 |
| First Named Inventor | Joseph R. Codispoti |
| Group Art Unit | 1614 |
| Examiner Name | D. Jagoe |
| Attorney Docket Number | MCP-264 |
| | |

| | | OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | ı |
|---------------------------------------|--|---|--|--------------|
| Examiner's | Cite | Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), | T ² | |
| Initials* | No.1 | publisher, city and/or country where published | L | ı |
| N | | Martindale, "The Complete Drug Reference, 1999, pp 443-444 | | |
| 007 | | Ellis et al., Annals of Emergency Medicine, 22(2), p. 191-95 (1993) | | |
| | | DF 0 | . A 4 | L |
| | | UEC n | } | |
| | <u> </u> | TE 0 | 2002 | ı |
| | | IECH MENT | 1 | 1 |
| | | + CENIFR. | 1000 | 1 |
| | | | 1 0U()/9 8 | $b \wedge a$ |
| | | | 7-9 | IUU |
| | | | | |
| · · · · · · · · · · · · · · · · · · · | | | I | 1 |
| | | | j | 1 |
| | | | ↓ _ | 4 |
| · · · · · · · · · · · · · · · · · · · | | | | 1 |
| | | | +- | 1 |
| | | | + | ╢ |
| | | | | 1 |
| | | | | 1 |
| | ↓ | | | ii ii |
| | | | | 1 |
| | | | + $-$ | 1 |
| | | | + | 1 |
| | + | | 1 | 1 |
| | + | | | 1 |
| | + | | | 1 |
| L | | | | n |

| Examiner Signature | Dunch | Date Considered | 1,0/03 |
|-----------------------|-------|--------------------|--------|
| | | - | (''' |

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

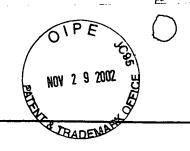
NOV 2 9 2002
SUBMISSION UNDER MPEP 609 D

CORP 1 of 1
U.S. PATE

| Application Number | 09/709,069 |
|------------------------|---------------------|
| Filing Date | 9 November 2000 |
| First Named Inventor | Joseph R. Codispoti |
| Group Art Unit | 1614 |
| Examiner Name | D. Jagoe |
| Attorney Docket Number | MCP-264 |
| | |

U.S. PATENT DOCUMENTS U.S. Patent Document Name of Patentee or Applicant Pages, Columns, Lines, Kind Code² Examiner Cite where relevant passages or relevant ligures appear of Cited Document Initials Number (if known) No.1 **FOREIGN PATENT DOCUMENTS** Foreign Patent Document Pages, Columns, Lines, where relevant passages Name of Patentee or Examiner Cite or relevant figures Applicant of Cited Document Office³ Number⁴ KindCode⁵ Initials appear No.1 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), Cite No.1 Examiner title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), T² volume-issue number(s), publisher, city and/or country where published Search Report dated 31 August 2001 for EP Appln. No. 00 31 0392 (European Equivalent to U.S. Serial No. 09/706,681 (MCP-263 US))

| | | | 1 | \sim | | | | | |
|---|-----------------------|---|----|--------|--------------------|----|-----|----|--|
| | Examiner Signature | λ | Ym | | Date Considered | // | 101 | 03 | |
| • | | | | 7 | | | | | |



SUBMISSION UNDER MPEP 609 D

Application Number 09/709,069
Filling Date November 9, 2000
First Named Inventor Codispoti
Group Art Unit 1614
Examiner Name D. Jagoe
Attorney Docket Number MCP264

Page 1 of 1

Examiner Initials No.1 Name of Patentee or Applicant of Cited Document Number (if known) Pages, Columns, Lines, where relevant figures appear

FOREIGN PATENT DOCUMENTS Foreign Patent Document Pages, Columns, Lines, where relevant passages Name of Patentee or Examiner Cite or relevant figures т Applicant of Cited Document Initials appear Office³ Number⁴ KindCode5 No.1 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), Examiner Cite title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), T² No.1 volume-issue number(s), publisher, city and/or country where published U.S.S.N. 09/706,681 (MCP-263) filed November 6, 2000 U.S.S.N. 09/448,988 (MCP-239) filed November 24, 1999 Center for Drug Evaluation and Research "Approval Letter" Application No. 20-492/SCM-001/S-002/S-003/S-004/S-005 (3/2000)

| | | | <u> </u> | | 1 . | |
|-----------|---|----|----------|------------|----------|--|
| Examiner | 7 | h. | h | Date | 1/10/12 | |
| Signature | | /m | 7 | Considered | ' 1/0/03 | |
| | | | | | | |

| · (PE | DEC 2002 | ,57 J |
|-------|-----------|-------|
| 7 | WY & TRAF | |

SUBMISSION UNDER MPEP 609 D

Page 1 of 1

| Application Number | 09/709,069 | |
|------------------------|--------------|---------|
| Filing Date | 9 Novemb r 2 | |
| First Named Inventor | Joseph R. Co | dispoti |
| Group Art Unit | 1614 | |
| Examiner Name | D. Jagoe | C |
| Attorney Docket Number | MCP-264 | 2 |

1614

D. Jagoe
MCP-264

Pages, Columns, Lines where relevant figures appear U.S. PATENT DOCUMENTS U.S. Patent Document Name of Patentee or Applicant Kind Code Cite Examiner of Cited Document Initials (if known) No.1 Number

FOREIGN PATENT DOCUMENTS Foreign Patent Document Pages, Columns, Lines, where relevant passages or relevant figures Name of Patentee or Examiner Cite Applicant of Cited Document appear Number⁴ KindCode⁵ Office³ No. 1 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), Cite No.1 Examiner title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published Codispoti, Joseph R., et al., "Efficacy of Nonprescription Doses of Ibuprofen for Treating Migraine Headache. A Ramdomized Controlled Trial", 41 Headache, 665-79, 2001

| Examiner Signature | Jack | Date Considered | 1/ | 10/ | 13 |
|-----------------------|------|--------------------|----|-----|----|
| | (| | | | |